EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
United States of America, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06–CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

[PROPOSED] UNITED STATES' REPLY IN SUPPORT OF ITS THIRD MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS FROM ABBOTT LABORATORIES INC. AND TO REQUIRE THAT ABBOTT DE-DESIGNATE NON-CONFIDENTIAL INFORMATION

The United States of America, through its undersigned counsel, respectfully files this [Proposed] Reply in Support of its Third Motion to Compel the Production of Documents from Abbott Laboratories Inc. ("Abbott") and to Require that Abbott De-Designate Non-Confidential Information. The United States has had to file a third motion in a series of motions to compel Abbott to produce documents in this matter.

The United States' Third Motion to Compel was filed on October 15 (Dkt. No. 4799); Abbott opposed the Motion on November 7. *See* Abbott's Response in Opposition to the United States' Third Motion to Compel Production of Documents (Opp.) (Dkt. No. 4876). The major reason for Abbott's Opposition is its contention that it has produced the vast majority of documents at issue. *See* Opp. at 1. This is simply untrue. To the contrary, for the categories of documents set forth in the United States' Motion, document production has not been completed. To be sure, the filing of the Motion spurred Abbott to produce some additional documents and data. However, Abbott still refuses to produce documents on Acyclovir Sodium–a recently

added subject drug, has omitted highly relevant information from its production of transactional data, has not produced (or explained the absence of) court-ordered and highly relevant marketing plans for the subject drugs, will not confirm for any single document request whether its production is complete, and continues to ignore direct questions of the United States on many areas of Abbott's document production, precluding resolution of outstanding issues by the parties.

Abbott's conduct has impeded the United States' ability to notice or complete depositions of fact witnesses within the discovery deadline of December 31 set by Judge Saris. Moreover, Abbott's insistence on marking virtually every document and deposition transcript in this case as Confidential (or Highly Confidential) is not only in contravention to the Protective Order and Judge Saris's recent rulings, it has the effect of preventing the United States from effectively and timely preparing its case for trial. Abbott's efforts to keep its documents and testimony of former and current Abbott employees secret during discovery (and eventually from the public eye at trial) is troubling; the United States again requests that these prior actions be reversed by the Court requiring Abbott to de-designate non-confidential materials, and to comply in good faith with Judge Saris's Orders in its future document productions.

Acyclovir Sodium

On June 4, 2007, the United States served its First Amended Complaint to include, among other changes, the addition of a single drug, Acyclovir Sodium, in the case. Abbott's Motion to Dismiss the First Amended Complaint (Dkt. No. 4469) and the United States' Opposition thereto (Dkt. No. 4661) is under consideration by Judge Saris. At the time of the filing of this Motion, the discovery cut-off in this case is December 31, yet Abbott has still not

served an answer to either the First or Second Amended Complaint. Abbott has stated that it will not produce transactional data or, presumably, documents relating to Acyclovir Sodium until Judge Saris rules on the pending Motion to Dismiss. *See* Opp. at 8.

Abbott should produce immediately all transactional data and documents related to Acyclovir Sodium for several reasons. First and foremost, there is no dispute between the parties that the data and non-privileged documents related to this drug, once added to the case, are relevant. Second, Judge Saris ordered discovery to proceed in this case while the first Motion to Dismiss was pending (CMO. 29, Dkt. No. 3956), and indeed discovery did proceed, and continues to move forward even though Abbott has not served the United States with an answer. Third, the current deadline for fact discovery is one month away (CMO. 29, ¶18, Dkt. No. 3956). Finally, Judge Saris signaled at the oral argument on Abbott's Motion to Dismiss that she likely would grant a motion for leave to amend the Complaint to include Acyclovir Sodium (Transcript of November 5, 2007 hearing, Ex. 2 at 4-5). The Court has not yet ruled on the United States' Motion for Leave to Amend, which was subsequently filed (Dkt. No. 4878).

Missing Transactional Data

The United States has requested since the outset of this litigation a complete set of Abbott's transactional data[1] for the subject drugs. After filing the current Motion, Abbott produced what it has represented to be the complete transactional data for the subject drugs. *See* Ex. 1 at 1 (Letter from Carol P. Geisler to Mark Lavine, dated November 5, 2007). The United

[1]A sales-related transactional data set is a set of electronic records in which each record: (1) represents a sales-related transaction between a firm and one of its customers, and (2) consists of data elements that characterize the transaction in sufficient scope and detail to support related business activities.

States immediately provided that data set to Dr. Mark Duggan, Ph.D., an economist and expert witness retained for this case to analyze Abbott's transactional data. *See* Ex. 10 (Declaration of Dr. Mark Duggan, dated November 27, 2007).

From his preliminary review of the data, Dr. Duggan has informed the United States that it appears that Abbott has omitted highly relevant information from the data set it produced to the United States when compared with the data set on the same drugs Abbott produced to the State of Texas in its AWP case, in or around May of 2007. *See State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v Abbott Laboratories Inc., Abbott Laboratories, and Hospira, Inc.*, Dist. Court of Travis County, Texas, 201st Judicial District (Cause No. D-1-GV-04-001286) (Texas case). *See* Ex. 10 at ¶¶ 3-6. Dr. Duggan has provided an expert report on the subject drugs (and additional drugs) in the Texas case, and thus previously has been provided the data set on drugs that overlap in both cases. *See* Ex. 10 at ¶ 2.

As Dr. Duggan elaborated further in his Declaration, Abbott placed zeroes (or eliminated figures) in a particular data field identified as "Rebate." *See* Ex. 10 at ¶ 5. However, information in the same "Rebate" field provided by Abbott to the State of Texas amounted to more than one-third of total sales. *See* Ex. 10 at ¶ 5. To illustrate these and other concerns with the data set recently produced by Abbott, the United States sent Abbott a letter and an Excel spreadsheet with the breakdown. *See* Ex. 8 (Letter from Renée Brooker to Jason Winchester and Carol Geisler, dated November 26, 2007). In short, there appears to be no correspondence between the sum in the Rebate fields in the two data sets. At no time did Abbott inform the United States or Texas that it would produce two different sets of transactional data on the same drugs.

The United States is concerned because Abbott has a demonstrated pattern of discovery

abuse, particularly related to this transactional data, for which the Court in Texas sanctioned Abbott.[2] *See* Memo at 4, fn. 2 (Dkt. No. 4800). In order to obtain a complete data set on the same drugs, the State of Texas had to depose, more than once, an Abbott corporate representative, and engage in extensive motions practice. *See* Memo at 4. Remarkably, it appears that the Plaintiffs' data requests may dictate the parameters of Abbott's data searches, even though Plaintiffs are necessarily dependent upon Abbott's knowledge of its data systems.[3] This suggests that Abbott may be taking advantage of the Plaintiffs' lack of knowledge of Abbott's data systems when searching and producing the data to be provided. Moreover, it appears that there may still be inaccuracies in the data Abbott provided the State of Texas now that it has been compared to the data recently produced in this case. *See* Ex. 10 at ¶ 7. For these reasons, the United States seeks to compel Abbott to produce a complete and accurate set of all

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[2]This is also the same pattern of conduct by Abbott in this case with regard to other documents unrelated to the transactional data at issue, namely the omission of relevant documents from its production set. As a result, Judge Saris ordered Abbott to produce documents it produced to the State of Texas and Relator, which it omitted from its production to the United States. *See* Memo at 2 (Dkt. No. 4800), *citing* Judge Saris's Orders at Ex. 7 at 1, and 7 at 3 (Judge Saris's 08/21/07 electronic Order on Relator's April 27, 2007 Motion to Compel Abbott to Produce or Consent to Access To and Sharing of All Discovery Produced by Abbott in Other False Price Report Litigation; and 09/06/07 electronic Order denying Abbott's Emergency Motion to Stay the Effect of and Motion to Reconsider the Court's August 21, 2007 Order).

[3]For example, after learning that it had received inaccurate transactional data from Abbott, the State of Texas reopened the deposition of its corporate designee, Bruce Stowell. *See* Ex. 9 (Deposition of Bruce Stowell dated August 30, 2007). Mr. Stowell testified "...we don't change what you guys [the State of Texas] ask for. We run what you ask for." Ex. 9 at 370:4-6. In addition, he testified that he "leave[s] the completeness [of the data searches] to the requestor." Ex. 9 at 320:18-24. When asked how he searches for data, he testified that "We always just pull what we are told to pull." Ex. 9 at 242:8-10. Further, he testified that he expected the State of Texas to recognize whether Abbott omitted transactional data from production. Ex. 9 at 381:21-382:18. The testimony of Abbott's corporate designee on its transactional data does not leave the Plaintiffs with much confidence in the data that is being searched for and provided.

transactional data on the subject drugs, including those for Acyclovir Sodium.

Marketing Plans

The United States informed the Court in its Motion that Abbott has not produced specific marketing plans that Abbott has repeatedly represented as the *only* marketing plans covering the subject drugs for the relevant years (1991-2003). On May 22, 2007, the Court ordered that these plans be produced by Abbott to the United States. Memo at 6 (Dkt. No. 4800). As Abbott is well aware, because it is a topic the parties have repeatedly discussed, the United States is seeking the documents that Abbott created annually and referred to as "August Plans" and "April Updates" (Annual Plans and Updates). Remarkably, Abbott's only response to the United States' Motion on the subject of these Annual Plans and Updates is evasive:

> To the extent documents exist evidencing marketing plans or strategies relating to these products, they have been produced to the Government (not to mention all of the depositions the Government has conducted on these issues), and that is all that can be required. There is no conceivable way for Abbott to comply with the Government's ludicrous demand that Abbott identify whether any other sales and marketing documents ever existed over the course of the last 16 years and then detail how and when they may have been lost or discarded.

Opp. at 4.

After the Court's May 22 Order, the United States sent a letter on August 31, 2007, specifically asking Abbott whether it could locate *any* copies of the Annual Plans or Updates, for the years 1991-1997 or 2001 (among others), copies of which it appears have been circulated widely within Abbott.[4] Memo (Dkt. No. 4800) at Ex. 4 at 120-122. Abbott has not responded to

[4]See, for example, the numerous marked-up copies of the "2003 Plan Update" produced from the files of several Abbott employees, which demonstrate the wide distribution of these Annual Plans and Updates. *See* Memo (Dkt. No. 4800) at Ex. 4 at 4-121.

the specifics of that letter. The United States is entitled to a direct response.

Abbott has been on notice of this lawsuit, and thus its preservation obligations, since at least 1996. *See* Ex. 5 at 50 (March 14, 2007 Deposition of Ellen Klaus, Abbott's document production corporate designee). Thus, Abbott understood its preservation obligations encompassed the marketing plans on the subject drugs. It seems inconceivable, given their likely (and apparently) wide circulation, that not a single employee has maintained a copies of the Annual Plans or Updates for the numerous missing years. Also, notably, Abbott has not produced a single copy of the Annual Plan or Update for the subject drugs for the year 2001– the year in which Abbott dramatically lowered its reported prices on the subject drugs, and arguably ceased reporting false prices. *See* Memo (Dkt. No. 4800) at Ex. 4 at 120-122. For these reasons, the United States renews its request that the Court order Abbott to certify that it has produced all documents covered by the Court's May 22 Order, and further, inform and certify to the United States whether the missing Annual Plans and Updates have been lost or destroyed, including the date and circumstances of that destruction.

Files of Alternate Site Salespersons

At a hearing on May 16, 2007 (Memo, Ex. 11, Tr. at 56), this Court ordered the production of the files of the salespersons who market the drugs at issue. *See* Memo (Dkt. No. 4800) at Ex. 3 at 5-6. Abbott, notwithstanding its Opposition, still has not confirmed the names of all the salespersons employed from 1991-2003, has not produced certain salespersons' files with missing information, and has not represented whether its production of all salespersons' working files, including their call notes, has been completed. *See* Ex. 3 at 2-8 (Correspondence in November 2007 from Rebecca A. Ford to Jason Winchester). For these reasons, the United

States renews its request that the Court order Abbott to identify all of its salespersons for the relevant years and produce or confirm production of all responsive documents. Further, if Abbott has lost or destroyed documents that fall within this category, the United States asks the Court to require Abbott to provide the specifics of that information.

Alternate Site Bottom 20% of Customers

This Court has ordered already that Abbott either stipulate that it will not introduce any evidence on this category of customers, or produce the documents. *See* Memo (Dkt. No. 4800) at Ex. 11 at 68. Abbott chose production over the stipulation. *See* Memo (Dkt. No. 4800) at Ex. 3 at 6. We request that the Court order Abbott to produce all documents that fall within this category, and not only documents that Abbott has selectively determined are relevant to the United States' case. *See* Opp. at 5.

Emails

In its Motion, the United States has questioned the completeness of Abbott's email production. *See* Memo (Dkt. No. 4800) at 3. Abbott's Opposition does not address this issue. The United States requests that Abbott be required to produce all emails in electronic format, and explain the reasons for missing, responsive emails, including the reason that emails prior to 2002 are not available in electronic format. *See* Ex. 4 (Correspondence relating to Abbott's email productions).

Hospital Products Division

Abbott claims that it has "searched within Abbott generally, regardless of division," and not only within Hospital Products Division. Opp. at 2. Representations of counsel in the Opposition to the Motion cannot be reconciled with the testimony of Abbott's corporate

designee, Ellen Klaus, on the subject of Abbott's document collection and production. Ms. Klaus was responsible for the retention, collection, and search for documents in response to the United States' earliest subpoenas dating back to 1996 to the present discovery requests. *See* Ex. 5 (March 14, 2007 Dep. Tr. 50). Abbott presented her as its corporate designee on these topics. Ms. Klaus testified that she worked with or spoke only to the Hospital Products Division in the collection, retention, or search for documents. *See* Ex. 5 (March 14, 2007 Dep. Tr. 50-51). Further, to the extent that Abbott searched in its off-site facility that stores all inactive or closed files for the company (known as Abbott corporate records), it searched for and collected "HPD's records retained in corporate records." *See* Ex. 5 (March 14, 2007 Dep. Tr. 62). Ms. Klaus repeatedly testified that "at this point we don't have any reason to look [elsewhere than HPD]." *See* Ex. 5 (March 14, 2007 Dep. Tr. 61). For these reasons, the United States cannot withdraw its request that this Court order Abbott to search more broadly for relevant documents beyond the Hospital Products Division.

Time Period

This Court has ordered Abbott to produce all responsive documents up to and including 2003. (Dkt. No. 4244). Recently, Judge Saris carved out a category of relevant documents for which a time period limitation should not be imposed, namely "all documents which refer or relate to Abbott's marketing a spread on a drug involving AWP no matter what drug or what year," and "with respect to the particular named drugs at issue in this litigation, [] all documents related to pricing that drug regardless of the time period generated." *See* Judge Saris Order on third party discovery, dated September 7, 2007 (Dkt. No. 4701). As there is absolutely no reason to extend that rule to third party productions, but not Abbott's document production, we ask that

this Court eliminate the 2003 time limitation for the categories of documents set forth in Judge Saris's Order.

Confidentiality Designations

Finally, the United States requested in its Motion that Abbott be required to review its prior wholesale designations of documents as confidential, and remove the designation for all documents that do not meet the terms of the Protective Order. *See* Memo (Dkt. No. 4800) at 9-11. Abbott has wielded the Protective Order in this case as authority to stamp virtually every page of material it produces in this case as Confidential or Highly Confidential. It apparently believes the burden is on the United States to review Abbott's entire production (and almost all deposition transcripts) and determine which designations are improper. Opp. at 8-9. The Protective Order cannot be read in this manner to eliminate entirely any good faith obligation of Abbott. To the contrary, the Protective Order requires that Abbott make good faith confidentiality determinations, and for good reason. *See* Protective Order, ¶ 3 (Dkt. No. 3804). The United States does not possess the information necessary to determine whether Abbott's company documents meet the standards set forth under the Protective Order.

Abbott's complaint with regard to the United States' requested relief is one of burden. Opp. at 8, 11. However, the burden to the Government and the Court in denying the relief is far greater. The United States would have to review Abbott's entire production and determine which materials do not meet the standards under the Protective Order and Judge Saris's rulings. *See* Memo at 9-10 (Dkt. No. 4800), *citing* Judge Saris's Orders. The United States does not wish to tie up this Court with a multitude of motions to de-designate confidential documents, which Abbott suggests as the appropriate remedy. Opp. at 8-9. Moreover, in the few limited cases

where the United States has raised objections to Abbott's confidentiality objections in the context of discovery, Abbott has simply ignored them. *See* Ex. 6 (Correspondence from counsel for the United States to counsel for Abbott challenging improper confidentiality designations of entire transcripts). Finally, Abbott cannot hide behind a burdensomeness objection when it is its own conduct that has caused the burden and required the United States to seek this specific relief.

Judge Saris has expressly ordered that such wholesale confidentiality designations cease. The parties have been given express guidance on what types of materials clearly should not be stamped as confidential. Since those rulings, there is no dispute that Abbott has produced thousands of pages of materials and continues to stamp almost every page confidential or highly confidential (*see e.g.*, Ex. 3-1), thereby ignoring Judge Saris's rulings; the same has been true of Abbott's designations of transcripts of depositions taken in this case. *See* Ex. 6.

There is authority for the type of relief sought by the United States in this case. The Court has inherent authority to "ensure that civil litigation is resolved not only fairly, but also without undue cost or delay." Fed. R. Civ. P. 1 (1993 Advisory Committee Notes). In an unpublished decision in *United States v. Philip Morris et al.*, the district court judge granted the very relief sought in the instant case and required Philip Morris to "conduct a review of all documents that Philip Morris has designated as [highly confidential] and produced to Plaintiff, and make any necessary downgrade in designation or de-designation required in accordance with the recommendation of the Special Master []."). *See* Ex. 7-10 (Order #218 granting the United States' Motion to Compel Philip Morris to Comply with the Protective Order). As a result of this order, Philip Morris was required to re-review and re-designate thousands of pages of materials, and re-produce them to the United States without the confidentiality stamp.

Finally, Abbott complains that there is no prejudice to the United States by its conduct in stamping every document and transcript confidential. This is not true. As the United States has set forth in previous filings, the abuse of a Protective Order such as that which has occurred in this case, prevents the United States from easily accessing and using the discovery to prepare its case. *See* United States' and Relator's Motion for Protective Order, dated September 15, 2006 (Dkt. No. 3105-3106). The *Philip Morris* decision describes the prejudice to the parties of such abuse.

> Particularly in trial preparation, where great volumes of documents are likely to be used by the parties, the over-designation of information could hamper a party's ability to adequately prepare, as well as the right of the public, if the information is used at trial, to have access to such information, particularly where the proceedings have significant public interest.

See Ex. 7-8. Indeed, every time the United States seeks to attach an exhibit to a motion or other filing in this case, it must consult with Abbott in advance to obtain approval to file the document. The problem is particularly acute because almost all of Abbott's documents have been marked "Confidential" or "Highly Confidential."

For these reasons, the United States asks this Court to exercise its authority to require Abbott to re-review its documents within twenty (20) days, and minimally comply with Judge Saris's Order by de-designating "all pricing information from more than 5 years ago," and "all commercial information from the 1990s." *See* Memo (Dkt. No. 4800) at Ex. 7-6 (Order dated October 10, 2007).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **[Proposed] United States' Reply in Support of its Third Motion To Compel the Production of Documents From Abbott Laboratories Inc. and To Require That Abbott De-Designate Non-Confidential Information** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Renée Brooker

Dated: November 28, 2007 Renée Brooker